

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/IB2004/001583

- Reference is made to the following documents:

D1: WO 00/20032

D2: J. of Allergy and Clinical Immunology, Vol. 110, no. 5, 2002, pages 757-762

- The present written opinion has been established with the assumption that the **priority date 24.04.03** is validly claimed. Therefore, document J. Biol. Chem., Vol. 278, no. 41, 10 October 2003, pages 40144-40151, has not been considered to be part of the prior art as defined in the regulations (**Rule 64 (1) and (3) PCT**).

SECTION V

- Novelty (Article 33(2) PCT)**

The present application does not satisfy the criterion set forth in **Article 33 (2) PCT** because the subject-matter of **claims 1, 2, 4-6, 8-10, 13-21** is considered to be part of the prior art as defined in the regulations (**Rule 64 (1)-(3) PCT**).

Both documents **D1 and D2** disclose the recombinant cat allergen Fel d 1, in which the two chains, chain 1 and chain 2, are expressed in series and linked together by a glycine/serine linker (i.e. a dipeptide). Unique restriction sites were designed on both sides of the linker.

The two polypeptide chains constituting the natural Fel d 1 are known and described extensively in the prior art, as acknowledged by the Applicant (page 4, lines 14-16 of the description). The sequence of chain 1 being SEQ ID NO:1 and the sequence of chain 2 being SEQ ID NO:2 or 3. Thus, it is implicitly disclosed in D1 and D2 that the rec Fel d 1 chains have the above sequences.

The recombinant Fel d 1 chains were successfully coexpressed in baculovirus, with comparable immunoreactivities to natural Fel d 1.

A pharmaceutical composition comprising said rec Fel d 1, as well as a method of diagnosing cat allergy are also disclosed.

Therefore, the subject-matter of **claims 1, 2, 4-6, 8-10, 13-21** is not novel over **D1**.

- Inventive Step (Article 33 (3) PCT)**

Claims 3, 7, 11 and 12 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step.

5. Industrial Applicability (Article 33(4) PCT)

- 5.1. The subject-matter of present **claims 1-18, 20 and 21** is susceptible of industrial applicability as defined in **Article 33 (4) PCT**.
- 5.2. For the assessment of the present **claim 19** on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

SECTION VIII

6. The present application does not satisfy the criterion set forth in **Article 6 PCT** because the following claims are not clear.
 - 6.1. The term "short" is without technical significance and is open to individual interpretation. Said term is vague and indefinite because it does not indicate the length of the peptide linker. Thus, it renders the subject-matter of **claim 1** unclear.
 - 6.2. The expression "fragment thereof" renders **claims 8 and 9** unclear. This expression is vague and indefinite because it does not indicate either the length of the fragment, the region of the Fel d 1 chain ½ to which the fragment corresponds, the function of fragment, or any particular characteristic/s that the fragment should have.
- 6.3. **Claims 8-10** lack clarity due to the expressions "homologue" and "homology". "Homology" has the precise meaning in biology of having a common evolutionary origin and should have no other meaning.

Homologous sequences are sequences which have a common evolutionary origin, but which need not to have any sequence identity at all nor need to have the same function.

Therefore, the expression "homologue...which provides substantially the same allergenic properties as..." (**claims 8 and 9**) and the expression "% of homology" (**claim 10**) have no meaning.

The above expressions are thus not suitable to clearly characterize the subject-matter of **claims 8-10**.

- 6.4. The applicant is informed that expressions like "preferably" and "particularly preferably" have no limiting effect on the scope of the claims, that is to say, the features following any such expressions are to be regarded as entirely optional (see the **Guidelines for Preliminary Examination (PCT) CIII 4.6**).

SECTION VII

7. Contrary to the requirements of **Rule 5.1(a)(ii) PCT**, the relevant background art disclosed in documents **D1 and D2** is not mentioned in the description, nor are these documents identified therein.

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8. In case of filling amended claims, the applicant is requested to take account of the above comments.

The attention of the Applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (**Article 34 (2)(b) PCT** and **Rule 70.2 (c) PCT**). In order to facilitate the examination of the conformity of the amended application with the requirements of **Article 34 (2)(b) PCT**, the Applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.